NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

SUPERIOR COURT OF NEW JERSEY

COUNTIES OF
ATLANTIC AND CAPE MAY

CAROL E. HIGBEE, P.J.Cv.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
(609) 343-2190

MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

CASE:	**Mace/Speisman/Sager v. Hoffman-La Roche**
DOCKET #:	**ATL-L-199-05, ATL-L-197-05, ATL-L-196-05**
DATE:	**March 16, 2010**
MOTION:	**Motion for Reconsideration of the October 28, 2009 Order Denying Judgment Notwithstanding the Verdict**
ATTORNEYS:	**Michelle Bufano, Esq. – Defendant**
	Mike Rosenberg, Esq. – Plaintiffs

Having carefully reviewed the papers submitted and any response received, I have ruled on the above motion as follows:

Nature of Motion

Defendant, Hoffman-La Roche ("Roche") filed this motion seeking the court to reconsider its October 28, 2009 order denying judgment notwithstanding the verdict and to enter judgment in Roche's favor.

Factual and Procedural Background

Plaintiffs, Kelly Mace, Lance Sager, and Jordan Speisman, are Florida residents who brought suit against Roche alleging Accutane caused them to develop inflammatory bowel disease ("IBD"). In October and November of 2008, this court presided over the trial, which was governed by Florida law. The jury returned a verdict in favor of each of the plaintiffs. Roche subsequently filed a motion for judgment notwithstanding the verdict, which the court denied on October 28, 2009. The court ordered as to Mace alone either a new trial on damages or a remittitur, but denied a new trial on liability as to all.

Prior to the trial of plaintiffs, there was a Florida state court case in which Adam Mason sued Roche alleging Accutane caused him to develop IBD. This trial also resulted in a judgment against Roche. The Mason case was on appeal in Florida during the post-trial motions in the current case. On October 27, 2009, the Florida First District Court of Appeal reversed the final judgment in favor of Mason, holding he was unable to establish proximate cause because the prescribing physician testified he would have prescribed Mason Accutane even if the warning provided that Accutane could cause IBD.

After the Florida District Court rendered its decision in Mason, Roche brought it to this court's attention. On November 13, 2009, the court had a phone conference with counsel and informed Roche it could file a motion for reconsideration based on the Mason decision. Roche filed the present motion on November 19, 2009.

In this motion, Roche argues Mason is binding on this court and the decision requires judgment to be entered in its favor. Defendant contends Mason reaffirms that under Florida law it is the plaintiff's burden to prove that a different warning would have resulted in the medication not being prescribed. Roche notes that each of the prescribing doctors in this case testified he

was aware IBD was a risk of Accutane and would still have prescribed Accutane to the patient-plaintiff. Roche argues that like Mason, the plaintiffs in this case are unable to establish proximate cause. Since plaintiffs cannot establish proximate cause, Roche reasons judgment in its favor should be granted.

In opposition, plaintiffs allege the evidence in the case below is sufficient to support the jury finding of proximate cause and therefore this motion for reconsideration should be denied. Plaintiffs argue the proximate cause determination is a two-step process. First, it must be shown the manufacturer of a drug failed to provide an adequate warning which led the physician to fail to warn the patient. The second step is to demonstrate that if a proper warning was given, the physician would have either not prescribed the drug, or would have changed the description given to the patient of the risks associated with the drug, and the patient, therefore, would not have taken the drug. Only if those two steps are met is proximate cause established.

Specifically, plaintiffs argue that had the prescribing-doctors been provided with information about the risk of IBD and Accutane, they still may have prescribed Accutane to the patient but would have first discussed the risk of IBD when giving "informed consent" information to the patient. Furthermore, plaintiffs' counsel notes each of the plaintiffs testified that had he/she been warned of the risks of IBD, then he would not have taken Accutane. Plaintiffs contend this is sufficient to establish proximate cause and support the jury verdict.

Plaintiffs further allege Mason is not binding on this court. Plaintiffs argue the Florida First District Court's analysis of the proximate cause issue is in conflict with both the law and policy as set forth elsewhere in Florida and in New Jersey. Since there is a conflict, plaintiffs allege this court does not need to follow Mason. Plaintiffs argue that since Mason is not binding

on this court and there is sufficient evidence to support the jury verdict, defendant's motion for reconsideration should be denied.

Roche's motion is based on new information, specifically the Mason decision. The Mason decision was rendered after this court denied Roche's motion for judgment notwithstanding the verdict. This Florida Court of Appeal decision is appropriate for the court to consider because it constitutes new information that the court could not have considered prior to the October 28, 2009 order. The court now must decide on this motion for reconsideration how the Mason decision in Florida impacts on these plaintiffs, all of whom are residents of Florida.

I. The Mason Decision

The jury award for Mason against Roche was appealed to the Florida First District Court of Appeal. That court held "[b]ecause Appellee presented no evidence from either treating physician that a differently worded warning would have resulted in either physician not prescribing Accutane for his extreme acne, Appellee failed to establish that the allegedly deficient warning was the proximate cause of his injury." Hoffmann-LaRoche v. Mason, No. 1D08-2032, 2009 Fla. App. LEXIS 15997, at * 2 (Fl. Dist. Ct. App. 1st Dist., Oct. 27, 2009).

The court found Mason presented evidence that the warning was insufficient because it stated there was a "temporal association" between IBD and Accutane and "temporal" did not adequately describe the relationship between Accutane and IBD. Id. at 3. The court then focused on the prescribing-doctor's testimony to determine proximate cause was not established. The doctor testified he understood the warning to mean there was at least a possibility of a causal relationship between IBD and Accutane. Id. at 5. The doctor also testified he would be willing to prescribe Accutane to his patients, including Mason, even if the warning provided Accutane causes IBD in rare cases. Id. Therefore, the court reasoned any inadequacies in the warning

could not have been the proximate cause of Mason's injuries because the doctor "understood that there was a possibility that use of the drug could lead to Appellee developing IBD and he made an informed decision to prescribe the drug for Appellee despite this risk." Id.

The reasoning in the opinion seems to be inconsistent with the prior high regard the Florida courts have had for the rights of patients to make the determination of whether or not to agree to any particular medical treatment after being told by the physician about the benefits and risks of a recommended treatment.

There are several questions this Court has that the Mason opinion does not address. First, the decision clearly does not hold the warning given by Roche was adequate as a matter of law. The fact that the warning in the label is available to physicians through the Physicians Desk Reference either in book form or electronically, as well as through other sources is common knowledge. It is well known that most physicians refer to the label for prescribing advice, although they may also get information about a drug from other sources, including their own clinical experience and from medical journals and literature.

Under the law of both Florida and New Jersey, the drug manufacturer has a duty to provide information about a drug's benefits and risks that the manufacturer knew or should have known in a way that a reasonable prescribing physician will be able to understand. The legal question of whether a specific warning was adequate is usually a jury issue. See e.g., Feldman v. Lederle Lab, 125 N.J. 117, 141 (1991) (quoting Abbot v. American Cyanamid Co., 844 F.2d 1108, 1115 cert. denied, 488 U.S. 908 (1988)); Dixon v. Jacobsen Mfg. Co., 270 N.J. Super. 569, 592 (App. Div. 1994); Torsiello v. Whitehall Laboratories, Div. of Home Products Corp., 165 N.J. Super. 311, 316 (App. Div. 1979); Felix v. Hoffman-La Roche, Inc., 540 So. 2d 102, 105 (Fla. 1989); Brito v. County of Palm Beach, 753 So. 2d 109, 112 (Fla. 4th DCA

1998). The jury is told to evaluate the adequacy of the warning in the label from a reasonable physicians viewpoint not from a patient's view.

This is known as the "learned intermediary" doctrine and it is the accepted standard in both New Jersey and Florida. The "informed consent" doctrine is also accepted in both Florida and New Jersey. It is the physician's job to translate her/his understanding of the benefits and risks of the drug to the patient who then has a right to consent to take the drug or decline to take it. See Niemiera v. Schneider, 114 N.J. 550, 562 (1989) ("[I]t would be the bitterest irony if the learned intermediary were to be excused from performing the very act that makes the product safe, that is, giving proper warning of the danger or side effects of the product."); Acuna v. Turkish, 192 N.J. 399, 414 (2007); Howard v. Univ. of Med. & Dentistry of N.J., 172 N.J. 537, 547 (2002); Matthies v. Mastromonaco, 160 N.J. 26, 36 (1999); Valcin v. Public Health Trust, 473 So. 2d 1297, 1302 (Fla. Dist. Ct. App. 3d Dist. 1984) ("No presumption of a valid consent will arise unless the consent is an informed consent."); Fla. Stat. §766.103(3) (2009). See also Products Liability Law §9.6 (David G. Owen, ed., 2d ed. 2008) ("A prescribing doctor is obliged under the law of torts to inform the patient of a drug's benefits and risks (as well as the benefits and risks of no treatment and alternative treatments), and to monitor how the drug affects the patient.").

The plaintiffs' position in both Mason and the Speisman, Sager, Mace cases was that Roche knew or should have known Accutane caused/triggered IBD and the words "temporally associated" underplayed the risk. In each case the jury found the warning was inadequate, as has every jury who has decided this issue.

The finding by the Florida Appellate Court in Mason was limited to the decision that there was no proximate cause link between this failure to warn and the plaintiff's injuries. There

is no reference to the question of general causation in the Mason decision. The Mason decision rests solely on the ruling by the Appellate Court in Florida that under the facts in Mason even if an adequate warning had been given that Accutane causes IBD, it would not have changed the result.

Mason received prescriptions from two different doctors. The second doctor, Dr. Counselman, admitted that he did not look at or know what the warning on IBD was when he prescribed the drug. If a doctor does not look at the drug manufacturer's warning, then even if an adequate warning was given, the doctor would not convey the information to his patient. Dr. Counselman never read the warning, and therefore, he never discussed the warning with Mason. If a physician does not even pay attention to or read what the manufacturer says about the risks, then an adequate warning would not change the decision to prescribe, or Mason's and his mother's decision that Mason would use the drug, because the doctor would not convey the information to the patient. Here, there is no proximate cause.

However, most of Mason's treatment was under the care of a dermatologist, Dr. Fisher, who started Mason on Accutane at age 15 and treated him for several years. The Mason decision places emphasis on the finding of the court that Dr. Fisher testified he understood the phrase "temporally associated" to mean that there was at least a possibility Accutane in rare instances could cause IBD. A review of Dr. Fisher's testimony, however, shows his testimony was contradictory. On direct exam when first asked about the warning he testified as follows:

> Q. Doctor between '91 and '96 when you were prescribing Accutane to Adam (Mason) the Roche label said "Accutane is temporally associated with inflammatory bowel disease" Did that tell you as a board certified dermatologist that Accutane caused inflammatory bowel disease?
> A. No to me that does not imply causation.

[Mason Trial Transcript 929:24-25, 930:1-5.]

In fact, earlier Dr. Fisher testified that he had no reason to doubt Mason's testimony that he never warned him about inflammatory bowel disease. Id. 922:16-19. Dr. Fisher acknowledged that Mason, while being treated by him, developed rectal bleeding and on another visit gastric upset and he knew these were potential problems, but he also testified: "And in terms of inflammatory bowel disease, I will – I will tell you I don't know whether I was - - I or anybody else was very much aware of that at that time." Id. 922:18-13. He further stated that if he had been told IBD could be caused by Accutane, he would have mentioned this risk to his patients. Mason Trial 931:8-19.

The Appellate Court's reliance on his "testimony" that the "temporally associated" language would have caused him to understand that Accutane in rare cases would possibly cause IBD primarily came from a "yes" answer to a leading question posed by defense counsel on cross-examination. Id. 945:9-12. It is hard to understand how the Court relied on this answer without comment on the other testimony Dr. Fisher gave in his own words on direct. In fact, although he made this admission on page 945 of the transcript, the entire exchange was as follows:

> Q: All right. Would you agree, Doctor, that regardless of whether the disease occurred while were you taking Accutane or months after you stopped taking Accutane or even years after stop -- you took Accutane, you would agree that this warning advises the physician that there is at least a risk that a person taking Accutane might develop inflammatory bowel disease? Is that a fair statement?
> A: To me it -- I -- I -- to me it says what it says. It says there is a temporal association with inflammatory bowel disease and Accutane, it does not imply causation. It does not -- temporally I would interpret temporally as to be within the same frame, not delayed several years, but to me that is what it says and it doesn't imply that one causes the other. It just implies that there is an association.
> Q: And when there is association you understand there is at least a possibility of a causal relationship?
> A: Exactly.
> Q: So the words "temporally associated" informed you that there is, A, an association between the two and the possibility that one caused the other?
> A: Yes

[Mason Trial Transcript 944:14-25, 945:1-12.]

The Mason opinion, as stated, focuses on Dr. Fisher's acknowledgment on cross-examination that the warning at the time he prescribed Mason Accutane would have caused him to know in rare cases Accutane could possibly cause IBD. The fact he gave no warning to Mason about this possibility, but stated if the warning had been stronger and said causation, he would have at least mentioned it to the patient when discussing the risks and benefits, is also not mentioned by the Florida court in its decision. Id. 928:23-25, 929:1-23, 931:8-19.

The last point focused on in the Mason decision is the testimony of Dr. Fisher that he still would have prescribed the drug even if the warning was as strong as plaintiff's experts testified it should be. This point is not contradicted. However, the Mason opinion ignores the fact that even if the drug was prescribed, the patient could choose not to take it, and there is no discussion of why this should not have been part of the proximate cause analysis.

II. Mason's Effect on the Cases of Mace, Speisman and Sager

A state court is in the same position as a federal court when it is trying to determine the law of a sister state. A federal court is bound by the decisions of the state's highest court, but if the state's highest court has not ruled on the issue, then the federal court is bound by the state's intermediate appellate courts unless it "is convinced that the state's highest court would decide otherwise." Gares v. Willingboro, 90 F.3d 720, 725 (3rd Cir. 1996). Therefore, a state court is to "look at the opinions of the state's highest court and, if it has not addressed the question, to predict how, in the light of developing law both within and without the state to date, it would decide." Fantis Foods, Inc v. North River Insurance Co., 332 N.J. Super. 250, 260-261 (App. Div. 2000).

The Florida Supreme Court has addressed the precedential value of opinions from the Florida District Courts of Appeal. The Florida Supreme Court has stated, "the decisions of the district courts of appeal represent the law of Florida unless and until they are overruled by this Court." Stanfill v. State, 384 So. 2d 141, 143 (Fla. 1980). In the absence of an inter-district conflict, Florida trial courts are bound by district court decisions. Weiman v. McHaffe, 470 So. 2d 682, 684 (Fla. 1985).

Plaintiffs argue this court is not bound by Mason because there is a conflict with prior Florida law. The conflict, plaintiffs allege, is due to Mason's failure to recognize a patient's right to make informed decisions concerning one's own medical treatment. Plaintiffs allege a conflict between Mason and the Fifth District case of Buckner v. Allergan Pharmaceuticals, Inc., 400 So. 2d 820 (Fla. 5th DCA 1981). In Buckner, plaintiff brought suit against the manufacturers of prescription steroids alleging she was prescribed and took the drug without an adequate warning being provided. 400 So. 2d. 820, 821 (Fla. 5th DCA 1981). The plaintiff further alleged the defendant manufacturers knew of the dangerous side effects, gave an adequate warning to the doctors, but also knew or should have known these warnings were not being adequately relayed to the consuming public. Id. The trial court dismissed the plaintiff's case for failure to state a cause of action and the appellate division affirmed. Id. The Fifth District held a manufacturer of a dangerous commodity, like a prescription drug, does have a duty to warn, but with prescription drugs that duty is fulfilled when the manufacturer provides an adequate warning to the prescriber of the drug. Id. at 822. This goes to the failure to warn standard, but here and in Mason the warning was not found to be adequate. However, the court reasoned:

> A doctor's duty is to inform his patient what a reasonable prudent medical specialist would tell a person of ordinary understanding of the serious risks and the possibility of serious harm which may occur from a supposed course of therapy so that the patient's choice will be an intelligent one,

> based upon sufficient knowledge to enable him to balance the possible risks against the possible benefits.

Buckner, at 823. Plaintiffs reason the Fifth District in Buckner recognized a patient's right to make informed decisions on medical treatment, something the Mason court ignores. Buckner goes to the issue of a doctor failing to tell the patient what the manufacturer told the doctor. If an adequate warning is given, there is no issue of proximate cause because there is no wrongdoing by the manufacturer.

For further support of the proposition that Mason creates a conflict, plaintiff cites In re Dubreuil, 629 So. 2d 819 (Fla. 1994). In that case, the plaintiff was admitted to the emergency room in advance stage of pregnancy and in need of a Caesarean section. Id. at 820. Plaintiff consented to the Caesarean section but due to her religious beliefs she withheld consent for the blood transfusion. The hospital then contacted the plaintiff's estranged husband who consented to the blood transfusion. The court ultimately held there was no abandonment that would override the patient's constitutional right to withhold consent for medical treatment. Id. For purposes of this case, plaintiffs point to the part of the decision in which the Florida Supreme Court stated, "We begin our analysis with the overarching principle that *article I, section 23 of the Florida Constitution* guarantees that 'a competent person has the constitutional right to choose or refuse medical treatment, and that right extends to all relevant decisions concerning one's health.'" Dubreuil, at 822 (citing In re Guardianship of Browning, 568 So. 2d 4, 11 (Fla. 1990)).

Plaintiffs point to these cases to show the clear precedent regarding a patient's right to be the ultimate decision-maker on whether to take a prescription medication to demonstrate why Mason is not binding on this court. The Mason decision fails to take into account the fact that plaintiff's mother testified she would not have allowed her son to take Accutane if provided with

information from their prescribing doctors that Accutane could cause IBD, and ignores Dr. Fisher's testimony he would have mentioned this to them if it was in the warning. Plaintiffs argue because this testimony is not taken into account the decision went against years of precedent in Florida about a patient's right to choose.

The Mason court says in the opinion that its standard of review is "de novo" which the Court implies allows it, as the fact finder, to disregard some of the evidence over other parts of the evidence. However, this is not the law of Florida or New Jersey on a motion made after a jury has rendered a verdict. The Mason decision cites Weinstein Design Group v. Cecil Fielder, 884 So.2d 990 (2004). That case says that summary judgment orders are reviewed de novo, but the court goes on to state that when reviewing a trial court's denial of a motion for a directed verdict:

> An appellate court must view the evidence and all inferences in a light most favorable to the non-movant and should reverse **if no proper view of the evidence** could sustain a verdict in favor of the non-movant. [Emphasis added].

Id. at 997. See also City of Lauderhill v. Rhames, et al., 864 So.2d 432, 434 (Fla. Dist. Ct. App. 4th Dist. 2003) (stating that not only must the appellate court "resolve all conflicts in the non-movant's favor," reversal is only appropriate when "there is no evidence to rebut" the movant's position) (emphasis added).

This court in reviewing the Mason decision finds that the appellate court chose to ignore the evidence (1) that the doctor did not believe that the warning meant there was an actual causal link between Accutane and IBD, (2) that the doctor would have given different information to his patients if he had different information about a link between Accutane and IBD, and (3) that if the patient and his mother were advised about a causal link between IBD and Accutane the patient would not have taken the drug.

This court finds that first the Mason decision ignores the strong judicial precedent in Florida that ultimately it is the patient who decides whether a medication should be taken or not and the role of the patient in the proximate cause analysis. This is contrary to the law in Florida as expressed by the Florida Supreme Court and other Florida courts. Second, the decision is contrary to Florida precedent because it looked at the evidence in a light most favorable to the movant instead of the non-movant. The defendant in the Mace/Speisman/Sager cases wishes this court to apply the Mason decision as binding precedent that the jury verdicts in Mace/Speisman/Sager must be reversed as similar snippets of testimony as those cited in the Mason decision were presented in these cases.[1]

Proximate cause, however, is always a fact sensitive decision. To use the Mason decision to reverse three jury verdicts and grant dozens more dismissals before trial, this court would have to apply Mason as a binding decision that finds no matter what other evidence exists and without regard to whether a different warning would be given and without regard to whether plaintiff would have not taken the drug if offered it with an adequate warning, that plaintiff has no case if the doctor admits that the words "temporally associated" might suggest that in rare cases Accutane could possibly cause IBD and that he/she would have prescribed the drug even if the warning was stronger. To dismiss these cases this court, based on the Mason decision, would consider only this evidence and ignore the fact that there is other evidence that supports a finding of proximate cause. That really cannot be what the Mason court intended.

The last reason for this court declining to find the Mason decision requires reversal of the jury verdicts in the Mace/Speisman/Sager cases is precisely because the opinion is about a lack of proximate cause, and there is no decision more ephemeral, fact sensitive, gut centered than a decision on proximate cause. This court, with respect for the Judges in the Mason case,

[1] In fact there are at least 30 other Florida plaintiffs who have cases pending.

recognizes that a decision as to whether proximate cause exists or does not exist is one of the most difficult to make.

The fact is that the decision is a short decision without any discussion of most of these legal principles in detail. The opinion is not signed. It is "*per curiam.*" This is not meant to be a precedential opinion. The use of *per curiam* opinions in complex cases that set forth changes in the law or set binding precedent is not favored. In Ricci v. Destefano, 530 F.3d 88, 93, (2d Cir. 2008), Judge Cabranes in a dissenting opinion stated:

> The use of *per curiam* opinions of this sort, adopting in full the reasoning of a district without further elaboration, is normally reserved for cases that present straight-forward questions that do not require explanation or elaboration.... The questions raised in this appeal cannot be classified as such, as they are indisputably complex and far from well-settled.

In fact, the Mason opinion is short, written *per curiam* and as previously stated, does not appear to have been expected to be precedent for rulings in a multitude of other cases. The leading scholars have puzzled over proximate cause. "Because it is always to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent, proximate cause is an elusive butterfly that e'er evades a net of rules." Products Liability Law §12.1 (David G. Owen, ed. 2d ed. 2008) (internal citations removed). Proximate Cause cannot be reduced to absolute rules." W. Page Keeton, Prosser and Keeton on Torts §42 (Dan B. Dobbs, Robert E. Keeton & David C. Owen, eds., 5th ed. 1984). There was evidence in the Mace/Speisman/Sager cases that could support a finding of proximate cause, if looked at in a light most favorable to the plaintiff.

CONCLUSION

This court will not find, for all the reasons stated above, that the Mason decision requires this court to reverse the jury verdicts rendered in Mace, Speisman and Sager because there is

evidence in each of these cases that supports the jury verdicts on the issue of proximate cause. Therefore, the motion for reconsideration is denied.

Carol E. Higbee

CAROL E. HIGBEE, P.J.Cv.